

**Amendment and Response**

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Serial No.: 09/446,323

Confirmation No.: 2155

Filed: March 20, 2000

For: DEVICE FOR TAKING AND EXAMINING SAMPLES

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**REMARKS**

The Office Action of February 26, 2003 has been received and reviewed. Prior to this Amendment and Response, claims 1-3, 7, 8, and 10-23 were pending (with claim 21 withdrawn from consideration). With claims 12 and 21 having been amended and claims 24-26 having been added, the pending claims are now claims 1-3, 7, 8, and 10-26. Reconsideration and withdrawal of the rejections, and entry and consideration of the new claims, are respectfully requested.

**SPECIFICATION OBJECTION**

The Office Action has objected to the language used within the Abstract. In particular, the use of "means" language within the Abstract is objected to. Applicants note that the M.P.E.P. states only that such phraseology as "means" and "said" "should be avoided," (M.P.E.P. § 608.01(b), emphasis added). However, there is no indication that this sort of language cannot be used. Moreover, Applicant submits that the Abstract, as presently drafted, serves the intended purpose of sufficiently describing "the disclosure to assist readers in deciding whether there is a need for consulting the full patent text for details," (*Id.* at 608.01(b)). For these reasons, Applicant submits that revision of the Abstract is not required.

**CLAIM REJECTIONS**

Claim 12 has been amended as indicated in Appendix A.

**The 35 U.S.C. § 102 Rejections****§ 102(b) Rejection (Smith et al.)**

Claims 1, 3, 8, 11-12, 19-20, and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Smith et al. (U.S. Pat. No. 4,534,939). Applicant traverses for at least the following reasons.

Each of independent claims 1, 12, and 19 is directed to either a device for taking and examining samples (claims 1 and 19), or a kit for preparing a device for taking and examining samples (claim 19). In each claim, a testing means, among other elements, is recited. The

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testing means is: "displaceable within the housing," (claim 1); "operable to be displaced after having been introduced into the housing," (claim 12); or "displaceable within the passageway of the housing," (claim 19).

The Office Action alleges that Smith et al. discloses a "testing means 74" and that the "testing means is a chamber defined by 60 and partition 38." However, reference numeral 74 is identified in the specification of Smith et al. as a "fluid reagent" (see, e.g., col. 5, line 55). The fluid reagent 74 is, during operation, "forced into the reaction chamber 50" to mix with the sample (see col. 8, lines 14-15).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* at §2131, citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The "testing means 40" claimed by applicant, however, is a feature for actually examining, observing, and/or evaluating the sample mixture (see, e.g., Specification: page 2, last paragraph; page 6, first paragraph; page 8, second paragraph; and Abstract). For instance, the testing means of the present invention allows the test result of the sample mixture to be "seen through a window or through a transparent design of the end of the testing means," (page 8, lines 10-11).

Neither the fluid reagent 74 or the "chamber defined by 60 and partition 38" of Smith et al. permits any examination, observation, or evaluation of the test results. As a result, Applicant submits that Smith et al. lacks at least the claimed "testing means" recited in claims 1, 12, and 19 and, therefore, cannot anticipate these claims. Moreover, claims 3, 8, 11, 20, and 22 are not anticipated as they each depend from one of claims 1, 12, or 19. Further, these dependent claims recite additional and unique subject matter. For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

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**§ 102(e) Rejection (Hessel et al.)**

Claims 1-3, 8, 11-12, 19-20, 22 were rejected under 35 U.S.C. § 102(e) as being anticipated by Hessel et al. (assumed to be U.S. Pat. No. 6,048,735; although the Office Action identified Hessel et al. as U.S. Pat. No. 4,534,939). Applicant traverses for at least the following reasons. While substantive remarks are provided below, Applicant does not admit that Hessel et al. is prior art and reserves the right to swear behind the document at a later date.

Each of independent claims 1, 12, and 19 is directed to either a device for taking and examining samples (claims 1 and 19), or a kit for preparing a device for taking and examining samples (claim 19). In each claim, a cartridge, among other unique elements, is recited. The cartridge: "during operation of the device, is displaceable within the housing," (claim 1); is "displaceable relative to the housing," (claim 12); or "during operation of the device, is displaceable within the passageway of the housing," (claim 19).

The Office Action alleges that Hessel et al. discloses a "plurality of cartridges 8" separated by dividers 18, and a piercing element that "sequentially pierces each divider 18 of each compartment 8 thereby displacing the compartments." Applicant submits, to the contrary, however, that it is the piercing element 7 and plunger 15 (see Figure 5 of Hessel et al.) that are displaced during use. There is, however, no teaching identified in Hessel et al. of the compartments 8 being displaced relative to the housing.

As a result, Applicant submits that Hessel et al. does not teach each and every element of claims 1, 12, and 19 and, therefore, fails to anticipate the claims. Moreover, claims 2-3, 8, 11, 20, and 22 are not anticipated as they each depend from one of claims 1, 12, or 19. These dependent claims further recite additional subject matter which is submitted to be patentable in view of Hessel et al. For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

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**The 35 U.S.C. § 103 Rejection**

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith et al. or Hessel et al. in view of Berger (U.S. Pat. No. 4,269,237). Applicant traverses for at least the following reasons.

Claim 7 depends from claim 1 and thus includes all the elements of that claim. As discussed above, neither Smith et al. nor Hessel et al. teaches each and every element of claim 1 (see e.g., remarks above regarding the displaceable testing means and/or the displaceable cartridge), nor do these documents *suggest* the recited claim elements. Nothing is identified within the teachings of Berger that remedies this deficiency. As a result, Applicant submits that Berger, in combination with either Smith et al. or Hessel et al., fails to render claim 7 obvious. Reconsideration and withdrawal of the rejection are thus requested.

**Claim 21**

Claim 21 has been amended as indicated in Appendix A. Rejoinder of this non-elected method claim is respectfully requested upon notice of allowance of any of the elected product claims. Notably, the non-elected method claim includes limitations of the elected product claims (see 1184 O.G. 86, citing *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 37 USPQ2d 1663 (Fed. Cir. 1996)).

**ALLOWED CLAIMS**

Applicant notes with appreciation the indication that claims 13-18 and 22 are allowed.

**NEW CLAIMS**

Applicant further requests entry and consideration of new claims 24-26. These claims include recitations identified above that distinguish over Smith et al. and Hessel et al. These claims also find support in the specification and claims as originally filed. For example, claim 24 includes subject matter originally found in claim 1, as well as throughout the specification and drawings (see e.g., paragraph spanning pages 5-6). Claims 25-26 find support, for example,

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at page 8 (first full paragraph), the paragraph spanning pages 5-6, and within the drawings.

Entry and consideration of these claims are respectfully requested.

**SUMMARY**

It is submitted that pending claims 1-3, 7, 8, and 10-26 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
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PATENT TRADEMARK OFFICE

26 June 2003  
Date

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, on this 26<sup>th</sup> day of June, 2003, at 2:00pm (Central Time).

By: Kelly McNulty  
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**APPENDIX A - CLAIM AMENDMENTS  
INCLUDING NOTATIONS TO INDICATE CHANGES MADE**

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Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

**In the Claims**

For convenience, all pending claims are shown below.

1. A device for taking and examining samples, comprising a housing (50) in which a cartridge (30), a testing means (40) and a sample-taking means (10) are positioned, wherein the cartridge (30), during operation of the device, is displaceable within the housing (50) such that a sample introduced by means of the sample-taking means (10) is operable to form a sample mixture with a content of the cartridge (30), and wherein the testing means (40) is displaceable within the housing (50).
2. The device according to claim 1, wherein the sample-taking means (10) is operable to be introduced into an open end of the housing (50) and further wherein the sample-taking means (10) comprises a thread (18) which cooperates with a corresponding thread (53) in the housing (50).
3. The device according to claim 1, wherein a sample-facing end of the sample-taking means (10) comprises a sample chamber (20).
7. The device according to claim 1, wherein one end of the cartridge (30) comprises an opening (32) which can be closed by means of a ball (33).

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8. The device according to claim 1, wherein the cartridge (30) has a bottom (34) operable to be perforated.

10. The device according to claim 1, wherein the testing means has the shape of a cylinder and has an end that tapers in the form of a truncated cone (41), wherein a tip thereof has an opening (42).

11. The device according to claim 1, wherein the testing means (40) is operable to be brought in contact with the content of the cartridge (30) if the sample-taking means (10) is arranged in the housing.

12. (AMENDED) A kit for preparing a ready-to-use device for taking and examining samples comprising :

- (a) a sample-taking means (10) for taking a sample;
- (b) a housing (50) with a cartridge (30) arranged therein, the cartridge being displaceable relative to the housing (50); and
- (c) a testing means (40),

wherein the sample-taking means (10) and the testing means (40) are introducible into the housing (50) and the testing means (40) is operable to be displaced after having been introduced into the housing (50).

13. A device for taking and examining samples, comprising a housing having positioned therein a cartridge, a testing means, and a sample-taking means, the sample-taking means comprising two half-tubes connected to each other, wherein the cartridge is displaceable within the housing such that a sample introduced by the sample-taking means is operable to form a sample mixture with a content of the cartridge, and wherein the testing means is displaceable within the housing.

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14. The device according to claim 13, wherein at least one of the two half-tubes comprises a first disk and a second disk defining a sample chamber.
15. The device according to claim 14, wherein the first disk comprises a sieve and an indentation, and further wherein an edge of the first disk comprises a cone-shaped ring.
16. The device according to claim 15, wherein the cartridge is cylindrically shaped and comprises, on one end, a truncated cone engageable with the cone-shaped ring.
17. The device of claim 13, wherein the two half-tubes are connected by a joint, and wherein the joint is selected from the group consisting of a film hinge and an elastic web.
18. The device of claim 14, wherein the first disk is coupled to the sample-taking means with predetermined breaking points.
19. A device for taking and examining samples, comprising:  
a housing having a first end, a second end, and a passageway extending between;  
a cartridge operable to be received in the first end of the housing, wherein the cartridge, during operation of the device, is displaceable within the passageway of the housing;  
a sample-taking means operable to be at least partially received in the first end of the housing, wherein a sample introduced by the sample-taking means is operable to form a sample mixture with contents of the cartridge; and  
a testing means operable to be received in the second end of the housing, wherein the testing means is displaceable within the passageway of the housing such that the testing means can be brought in contact with the sample mixture.



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20. The device of claim 19, wherein the sample-taking means couples to the first end of the housing.
21. **(AMENDED)** A method for taking and examining samples, comprising:  
collecting a sample in a sample-taking means;  
coupling the sample-taking means to a first end of a housing, the housing having a cartridge located therein;  
displacing the cartridge relative to the [sample taking means] housing;  
combining the sample and contents of the cartridge to form a sample mixture;  
providing a testing means at a second end of the housing; and  
displacing the testing means relative to the housing, whereby the testing means contacts the sample mixture.
22. The device according to claim 1, wherein the testing means (40) is displaceable within the housing (50) between a first position, in which the testing means (40) does not contact the sample mixture, and a second position in which the testing means (40) makes contact with the sample mixture.
23. The device according to claim 13, wherein the testing means is displaceable within the housing between a first position, in which the testing means does not contact the sample mixture, and a second position, in which the testing means makes contact with the sample mixture.
24. **(NEW)** A device for taking and examining samples, comprising:  
a housing having a first end, a second end, and a passageway extending between the first end and the second end;  
a cartridge operable to be received in the first end of the housing, wherein the cartridge, during operation of the device, is displaceable along a portion the passageway of the housing;

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a sample-taking means operable to be at least partially received in the first end of the housing, wherein a sample introduced by the sample-taking means forms a sample mixture with contents of the cartridge; and

a testing member operable to be received in the second end of the housing, wherein the testing member is displaceable along the passageway of the housing such that the testing member can be brought in contact with the sample mixture.

25. (NEW) The device of claim 24, wherein the testing member comprises an elongate member comprising a test strip.

26. (NEW) The device of claim 25, wherein the elongate member is cylindrical in shape.